ity to understand and complete six consent tasks. They also provided information about themselves (maternal education, willingness to enroll child in a clinical trial) and their child (age, autism status, thinking/reasoning ability, gender). **RESULTS:** Factor analysis confirmed that the six items comprise a single factor. However, we found a clear hierarchy of difficulty; the least difficult tasks were "understands that this medication is different from his/her regular treatment" and "realizes that he/she can choose to participate in the study or withdraw at any time." The most difficult were "can make a decision about study participation" and "understands and weighs potential benefits and risks of participating in the study." Although 29% of parents reported that their son was not at all capable of participating, the remainder exhibited a range of decisional skills. Factors associated with this variability include gender, autism, cognitive ability, age, and parents' willingness to enroll their child in clinical trials. **CONCLUSIONS:** Parents rate many individuals with FXS as able to participate in the consent process, but they will likely need support to maximize effective participation. We conclude with a brief review of strategies to support more inclusive participation in the consent process for people with ID.

PRM163

RESULTS OF A STUDY USING A TABLET PC TO COLLECT PROS IN ELDERLY POPULATION

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OBJECTIVES: Primary objective of the Percepolis study was to look at patient's perception regarding their Erythropoiesis Stimulating Agents (ESA) treatment of anemia in chronic kidney disease. Many discussions arose at the set-up of the study regarding the best collection method of PROs as target population was old. The following factors helped to make a decision towards ePRO: - Clinical data were collected using an eCRF and previous experience of studies using PROs showed it was difficult to mix method of collecting data, - PRO was the primary endpoint of this study and needed to be carefully monitored, - Most elderly people use new technologies (cellular phone, PC), - Twenty questionnaires needed to be equally distributed. **METHODS:** This is a 6-month multicenter prospective Non-Interventional Study (NIS). Patients had to complete questionnaires at baseline and around 6-month in order to analyze the importance they gave to their ESA treatment characteristics. Technology used was the Tablet PC Samsung Galaxy Tab and specific interface was developed on the Operating System (O.S.) Android to maximize ease of use of the device for patients and investigators. For example, patients only had to select an answer on the screen to display the next question using the tactile functionnalities of the device. When connecting to the electronic data capture system, O.S. was detected in order to fit the screen's display of the HTML pages. **RESULTS:** A total of 789 patients were included, 93% patients answered at least one questionnaire at baseline, 87% after 6 months of treatment. Mean age of the study population was 73 years old (± 13 years). Most PROs (95%) were answered using the Tablet PC. **CONCLUSIONS:** ePROs can be used in elderly population as long as tools are adequately developed to simplify use of devices. ePROs also allowed following online study recruitment and questionnaires data entry.

PRM164

HOW BURDENSOME IS COMPLETION OF ELECTRONIC PATIENT-REPORTED OUTCOMES (EPRO)? ITEM COMPLETION TIMES AND QUALITATIVE EVIDENCE FROM STUDIES IN FOUR DIFFERENT HEALTH CONDITIONS

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OBJECTIVES: The patient burden of completing large numbers of patient-reported outcome (PRO) items is often a concern; particularly when PROs must be completed daily, or at multiple timepoints over long studies. However, as ePRO and mPRO (technology that utilizes patients' personal tablets and smartphones) methods advance, PRO completion becomes quicker and easier. How long does it actually take patients to complete ePROs? How burdensome do patients find ePRO completion? **METHODS:** ePRO allows collection of the time taken to complete a set of PRO items. We summarise data from four qualitative studies across a range of health conditions (fibromyalgia, a women's health condition, pediatric constipation and pediatric irritable bowel syndrome). In all four studies, small samples of patients (n=20-65) completed an ePRO diary daily for 5-9 days during pilot testing prior to cognitive debriefing. Completion times and missed days were collected. During the cognitive debriefing interviews patients were asked how burdensome the PRO completion was and if they had difficulty fitting it into their daily routine. **RESULTS:** The PROs being developed had 15-35 items, but two included skip patterns, reducing the item burden. Average completion times ranged from 2.5-5.5 minutes per diary. For diaries without skip patterns, mean 'per item' completion times were calculated to range from 9.4-15.7 seconds. The majority of patients (93-100%) reported that the PRO was quick and easy to complete and not burdensome. Missed diary rates were consistently low with only 0-12% of patients missing more than one diary completion in the two studies where this information was collected. **CONCLUSIONS:** These data provide evidence that patients (including children) can complete ePRO diaries very quickly, don't find this burdensome, and are happy to complete relatively large numbers of items daily. If ePROs are carefully designed, using skip-patterns and event driven items, completion burden can be reduced even further.

PRM165

HARMONIZING MEASUREMENT OF ADHERENCE ACROSS THE 4-ITEM AND 8-ITEM MORISKY MEDICATION ADHERENCE SCALE USING CROSS-SECTIONAL DATA FROM PATIENTS TREATED FOR IRRITABLE BOWEL SYNDROME

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OBJECTIVES: The 4-item Morisky Medication Adherence Scale (MMAS-4) and the more recent 8-item version (MMAS-8) have been both validated, and their concurrent validity has been assessed among hypertensive patients, but the extent to which the two scales can be compared against one another has not been determined. The current analysis assessed whether adherence scores obtained with the two scales on different patients can be compared or integrated across studies. **METHODS:** Data were taken from the 2011 and 2012 US National Health and Wellness Survey (NHWS). The NHWS is a large cross-sectional survey representative of the total adult population in several major markets; current analyses were limited to the US (n~75,000/year). Respondents self-reported physician diagnosis of various health conditions, including 9,633 who reported a diagnosis of IBS. Adherence was measured with MMAS-4 in 2011 and MMAS-8 in 2012. The two adherence scales were evaluated by comparing the frequency distributions of the MMAS scores in the two scales, Cronbach's alpha and inter-item correlations, and the creation of a new 4-item scale including the questions in MMAS-8 that best matched the questions in MMAS-4. **RESULTS:** In IBS patients, both MMAS-4 and -8 scores are Poisson-like distributed, with median at zero (high adherence). Chronbach's alpha was 0.64 for MMAS-4 and 0.70 for MMAS-8, while average item-test correlations were 0.70 and 0.59, respectively. The reduced 4-item scale created out of MMAS-8 is also Poisson-like distributed, Cronbach's alpha was 0.67 and the average item-test correlation was 0.71. **CONCLUSIONS:** Data obtained with the two MMAS show similar qualitative and quantitative characteristics, suggesting that it may be appropriate to integrate data sources using the two different versions, particularly when the responses to the subset of 4 MMAS-8 items are available. Future research should confirm that the scales can be integrated in different therapeutic areas.

PRM166

USING FEEDBACK FROM PATIENTS IN DETERMINING SUITABILITY OF THE PERCEIVED DEFICITS QUESTIONNAIRE (PDQ) AND THE RESOURCE UTILIZATION IN DEMENTIA-LITE (RUD-LITE) FOR USE IN CLINICAL TRIALS IN PRODROMAL ALZHEIMER'S DISEASE

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OBJECTIVES: Many instruments used to assess outcomes of treatment for Alzheimer's disease (AD) have no published evidence for their content validity in mild cognitive impairment (MCI) or prodromal AD (pAD). The objective of this project was to evaluate the content validity of AD patient reported outcome (PRO) instruments in this population. **METHODS:** Two waves of interviews were conducted: First, 11 patients with MCI and their informants/ (carers) evaluated several AD PROs (Alzheimer's Disease Medication Administration Questionnaire (ADMAQ), Abbreviated Resource Utilization in Dementia-Lite (RUD-Lite), Perceived Deficits Questionnaire (PDQ), and Abbreviated Dependence Scale (AB DS); Second, 8 patients with pAD reviewed the modified PDQ, and their carers reviewed the RUD Lite. Interviews were transcribed and analysed. **RESULTS:** Results of Wave 1 identified the PDQ and the RUD-Lite as the most promising measures for this cohort. Some minor modifications were suggested for the PDQ, and a separate section was added to the RUD-Lite. Results of Wave 2 showed pAD carers viewed the content of the RUD- Lite as less relevant because the patients are not functionally restricted enough to utilize resources at this early stage of the disease, although the newly added domain for the pAD population was understood and applicable. The modified PDQ was more acceptable to pAD patients than the original version. **CONCLUSIONS:** Even well-established measures for AD patients should have their content validity evaluated prior to their use in pAD or MCI populations. In this study, we found that the PDQ and RUD –Lite needed modifications to be more relevant in early stage patients.

PRM167

RECOMMENDATIONS FOR THE SUCCESSFUL LINGUISTIC VALIDATION OF CLINICAL OUTCOME ASSESSMENTS FOR LIMITED PATIENT POPULATIONS

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OBJECTIVES: Timeline and budget considerations for the linguistic validation of Clinical Outcome Assessments (COAs) can vary substantially depending on patient population requirements and target locales. Rare diagnoses and/or small populations of native speakers of a language can lead to a small pool of eligible patients for cognitive debriefing respondents. This review highlights considerations necessary to promote successful linguistic validation projects and mitigate the potential impact of small patient populations that, in turn, can affect study timelines as a whole. **METHODS:** To assess possible steps to take during study planning and the linguistic validation process, a literature review and examination of past linguistic validation projects were completed. This focused on trials in which a small patient population limited the number of eligible cognitive interviewing respondents, and the issues and solutions associated with each project. **RESULTS:** In order to meet timeline and budget requirements, it is crucial that sufficient steps are taken to ensure cognitive interviewing populations are fully evaluated during a trial's planning stages. Solutions for helping achieve this include: 1) Identification and possible inclusion of broader patient populations with conditions with similar symptoms; 2) Extended timeline consideration for rare diseases or small native-speaking populations at study start; 3) Selection of more general COAs (e.g. not specific to the diagnosis in the case of rare conditions) so cognitive interviewing may be performed on healthy respondents or a broader group of patients. **CONCLUSIONS:** When choosing COAs for global use, an analysis of the intended patient population – including prevalence rates of the condition and size of the native-speaking population – is recommended in order to integrate projected linguistic validation timelines into the overall study plan. It is also recommended that study teams discuss this with their language services team for guidance on timelines and assistance in planning to ensure targeted study milestones are met.

PRM168

USING MOBILE TECHNOLOGY (MHEALTH) TO DEVELOP THE VALUE STORY FOR NEW DRUGS, DEVICES AND THERAPIES: OPTIMISING USER ENGAGEMENT AND ADDRESSING PAYER CONCERNS

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